DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 14, 2014

Mindray DS USA, Inc.
Diane Arpino
Directory, Regulatory Affairs
800 MacArthur Blvd.
Mahwah, New Jersey 07430

Re: K142601
Trade/Device Name: Panorama Patient Monitoring Network
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, MLD, DSI, DRG, DQA, DQK, DPZ, DSK, DXN, CCK, NHO, CBQ, NHQ, NHP, CBS, CBR, CCL, DRT, DQA, MUD, FLL, GWM, DSB, DXG
Dated: September 10, 2014
Received: September 16, 2014

Dear Diane Arpino,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Panorama Patient Monitoring Network

Indications for Use:

The indications for use for the Panorama Patient Monitoring Network include:

- Viewing real time patient clinical and demographic data
- Graphical and numeric trending of clinical data
- Storing and printing of clinical and demographic data
- Setting independent alarm limits for data sent by the bedside monitor

The clinical data displayed by the Panorama Patient Monitoring Network is obtained from one or more compatible physiological monitors and includes: ECG waveforms Invasive and Non-Invasive Blood Pressure, Blood Oxygenation (SpO2), Heart Rate, Respiration Rate, Respiration Gasses, Temperature, Carbon Dioxide, , inspired and end tidal, Ventricular Arrhythmia analysis,ST Segment analysis, Arrhythmia Detection derived from 3/5 lead measurements, Cardiac Output, and Anesthetic Gas, and Pulse Rate.

The Panorama Patient Monitoring Network is intended for use in a fixed location, in the healthcare facility setting, as a central viewing station. The Panorama Patient Monitoring Network is not intended to be directly connected to the patient at any time or installed in a patient's vicinity.

The Panorama Network includes the Panorama Telemetry System which acquires and monitors physiological data for ambulating patients within a defined coverage area. The system processes the physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations. The Panorama Telemetry System is intended for installation in a hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored include ECG, blood oxygenation (SpO2), Heart Rate, Lethal and Non-Lethal Arrhythmia Detection and ST Segment Analysis. Received data is sent to the Panorama Server for ECG processing via Ethernet. This information can be displayed, trended, stored and printed at the Panorama Central Station.

The Panorama Monitoring Network is intended for use under the direct supervision of a licensed healthcare practitioner.

Prescription Use __X___ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Panorama Patient Monitoring Network

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

Date: August 15, 2014

Submitter:
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Mindray DS USA, Inc.
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Telephone: 201-995-8391
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Device Trade Name: Panorama Patient Monitoring Network

Common Name: Central Station Monitor and Telemetry System

Device Classification:

Primary:
§870.1025- MHX –Physiological Monitor (with Arrhythmia detector and alarm)

Secondary:
§870.1025- MLD - ST Segment with Alarm Monitor
§870.1025- DSI - Arrhythmia Detector and Alarm
§21 CFR 870.2910- DRG - Radiofrequency physiological signal transmitter and receiver
§21 CFR 870.2700- DQA - Oximeter
§870.1425- DQK - Programmable Diagnostic Computer
§870.2700- DPZ - Ear Oximeter, Pulse
§870.1110- DSK- Blood Pressure Computer
§870.1130- DXN - Non-invasive Blood Pressure Measurement System
§868.1400- CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
§868.1500- NHO/CBQ/NHQ/NHP - Enflurane Gas Analyzer
§868.1620- CBS - Halothane Gas Analyzer
§868.1700- CBR - Nitrous Oxide Gas Analyzer
§868.1720- CCL - Oxygen Gas Analyzer
§870.2300- DRT - Cardiac Monitor (Incl. Cardiotachometer and Rate Alarm)
§870.2700- DQA- Oximeter Sensor
§870.2700- MUD- Oximeter, Tissue Saturation
§880.2910- FLL - Clinical Electronic Thermometer
§822.1620- GWM – Intracranial Pressure Monitoring Device
§870.2700- DSB- Impedance plethysmograph

§870.1435- DXG- Single-function, preprogrammed diagnostic computer

Predicate Devices:

ViewPoint Central Monitoring System (marketed as the Panorama Patient Monitoring Network) – K031760

Hypervisor VI Central Monitoring System (including telemetry pulse oximetry) – K080192

Device description/ Indications for Use:

The indications for use for the Panorama Patient Monitoring Network include:
A. Viewing real time patient clinical and demographic data
B. Graphical and numeric trending of clinical data
C. Storing and printing of clinical and demographic data
D. Setting independent alarm limits for data sent by the bedside monitor.

The clinical data displayed by the Panorama Patient Monitoring Network is obtained from one or more compatible physiological monitors and includes:

- ECG waveforms,
- Invasive Blood Pressure
- Non-Invasive Blood Pressure,
- Pulse Oximetry(SpO2),
- Heart Rate
- Respiration Rate,
- Respiration Gasses,
- Temperature,
- Carbon Dioxide (CO2),
- Ventricular Arrhythmia analysis,
- ST Segment analysis from 3/5 lead measurements,
- Arrhythmia Detection derived from 3/5 lead measurements,
- Cardiac Output (CO), and
- Anesthetic Gas (AG)
- Pulse Rate (PR)

The Panorama Patient Monitoring Network is intended for use in a fixed location, in the healthcare facility setting, as a central viewing station. The Panorama Patient Monitoring Network is not intended to be directly connected to the patient at any time or installed in a patient's vicinity.

The Panorama Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes the physiological data to

detect various ECG arrhythmia events and select physiological parameter limit violations.

The Panorama Telemetry System is intended for installation in a hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored include ECG, blood oxygenation (SpO2), Heart Rate, Lethal and Non-Lethal Arrhythmia Detection and ST Segment Analysis. Received data is sent to the Panorama Server for ECG processing via Ethernet. This information can be displayed, trended, stored and printed at the Panorama Central Station.

Technological Comparison to Predicate Device:

The Panorama Network is equivalent to the predicate device the ViewPoint Central Monitoring System respecting the indications for use, basic operation, performance specifications, technology and materials (patient contacting). There are no changes to the device's intended use and fundamental scientific technology relative to the predicate device.

The Hypervisor Central Monitoring System serves at the predicate relative to Telemetry monitoring for SpO2.

Technology	**Subject / Panorama Patient Monitoring Network**	**Predicate / ViewPoint Central Monitoring System K031760**	**Predicate / Hypervisor Central Monitoring System (including telemetry pulse oximetry) K080192**
Indications for Use	Viewing real time patient clinical and demographic data Graphical and numeric trending of clinical data Storing and printing of clinical and demographic data Setting independent alarm limits for data sent by the bedside monitor. .	Viewing real time patient clinical and demographic data Graphical and numeric trending of clinical data Storing and printing of clinical and demographic data Setting independent alarm limits for data sent by the bedside monitor.	The Central Monitoring System (CMS) network transfers information between the Hypervisor VI Central System and other network devices. It also allows information transfer between several CMS. Network connections consist of hardwired network cables and/or WLAN connections. CMS can be used for remote monitor management, storing, printing, reviewing or processing information from networked devices, and it is operated by medical institutions. Telemetry System is a sub-system of CMS, intended to obtain ECG and SpO2 physiological information from

			adult and pediatric patients, and send it to CMS via WMTS frequency with a defined coverage area.
Central Station Telemetry Server TIM Transceiver Keyboard Mouse Display Operating System Longview-VGA extender	2U (Horizontal) or Vertical Tower 2U (Horizontal) Tower Yes Yes Yes Touch screen Windows XPe (embedded) Yes	Vertical Tower only Vertical Tower only Yes Yes Yes Touch screen Windows NT No	N/A
Telemetry System TIM Transceiver Frequency Repeater Antenna	2U (horizontal rack mount) 4U (horizontal rack mount) WMTS Yes Radio Frequency	Vertical Tower 4U (horizontal rack mount) 2.4 GHz No Radio Frequency	N/A
Telepack SpO2 Module	Telepack-608(WMTS) Yes	Telepack (2.4 GHz) No	TMS-6016 (WMTS) Yes
Accessories (used with Telepack)	ECG Electrodes ECG Lead Wires SpO2 Sensor	ECG Electrodes ECG Lead Wires	ECG Electrodes ECG Lead Wires SpO2 Sensor

Summary of Performance Testing:

The Panorama Network has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.

A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been verified and validated in accordance with the appropriate test requirements.

The Panorama Network has been tested and complies with the following recognized consensus standards:

- IEC60601-1
- IEC60601-1-2
- IEC60601-1-4
- IEC60601-1-8
- EC13
- EC53
- EC57
- ISO 80601-2-61
- ISO14970
- ISO15223

The Panorama Network was tested and complies with established parameter performance specifications respecting ECG, Arrhythmia analysis, ST Segment analysis and SpO2.

No clinical tests were performed on the Panorama Network. The substantial equivalence of the central monitoring networks has been long established through analysis of end-user experience and feedback gained through post-market analysis.